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| EXAMINER |
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MELLER, MICHAEL V

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| ART UNIT | PAPER NUMBER |
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1655

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08/11/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/591,023

Applicant(s)

ACHARYA ET AL.

Examiner

Michael V. Meller

Art Unit

1655

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 8, 15 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 8, 15, 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 4, 8, 15, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Upadhyay et al. in view of De Souza et al.

Upadhyay teaches that *Tinospora sp.* has been widely used in traditional Indian medicine for treatment of urinary tract infections, see col. 2, lines 25-40. Note also that *Tinospora cordifolia* is noted as protecting mice against *E. coli* induced abdominal sepsis. Thus, Upadhyay recognized the ability of *Tinospora cordifolia* as an anti-bacterial (anti-*E. coli*).

Upadhyay does not explicitly teach that *Tinospora cordifolia* is used to treat urinary tract infections or that the urinary tract infections are "chronic recurrent",

that an antibacterial agent such as amoxicillin is used along with the extract, or that the extracts are standardized by bioassay.

De Souza teaches that an extract of *Tinospora cordifolia* is standardized by bioassay. It is administered to humans, see abstract, example 5, paragraphs 1, 27-28, 31, 38-40, 44-50, 54, 60, the claims. It is also taught that the extract is administered along with conventional therapy such as penicillins, see paragraph 48 and example 5.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to standardize the extract of *Tinospora cordifolia* of Upadhyay since De Souza makes it clear that *Tinospora cordifolia* is routinely standardized by bioassay. Further, De Souza teaches a bioassay which evaluates the bioactivity by determining the percentage of phagocytosis over a base line, wherein the percentage of phagocytosis is not less than 20 % over a base value, see paragraph 44.

Also Upadhyay teaches that plants of the *Tinospora* species have been widely used in traditional Indian medicine for treatment of urinary tract infections which would include using *Tinospora cordifolia* since *Tinospora cordifolia* was just mentioned a few lines above that as a preferred plant in the genus of *Tinospora*. Clearly one of ordinary skill in the art would have contemplated *Tinospora cordifolia* as one of the species in the *Tinospora* genus to be used for

the treatment of urinary tract infections. Further, it clearly would have been within the purview of the ordinary artisan to use the extract for chronic recurrent urinary tract infections since the extract is already noted to be used for urinary tract infections and thus to use the extract for chronic recurrent urinary tract infections is obvious since knowing that the extract is widely used in Indian medicine for urinary tract infections it would also be obvious to use the extract for chronic recurring infections since these type of infections are chronic many times and do reoccur. To use an antibacterial such as amoxicillin is obvious since it is noted in De Souza to use penicillins as conventional therapy with the extract and to use a well known penicillin such as amoxicillin is well within the purview of the ordinary artisan since amoxicillin is one of the well known penicillins.

Since De Souza does teach using antibacterials to treat the infection, then inherently the E. Coli and Klebsiella infections will be treated as well.

Applicant argues that Upadhyay makes reference to *Tinospora* species in general and urinary tract infections are mentioned as one of several diseases in the treatment of which plants of *Tinospora* species had been used. Applicant further argues that there is no teaching that the plant *Tinospora corodifolia* could be used to the treatment of urinary tract infections and that there is no reasonable basis to interpret this to indicate that all *Tinospora* species were considered useful for all of the indicated conditions.

While these arguments are noted they are not persuasive. Upadhyay makes it clear that *Tinospora sp.* has been widely used in traditional Indian medicine for treatment of urinary tract infections, see col. 2, lines 25-40. Also Upadhyay teaches that plants of the *Tinospora* species have been widely used in traditional Indian medicine for treatment of urinary tract infections which would include using *Tinospora cordifolia* since *Tinospora cordifolia* was just mentioned a few lines above that as a preferred plant in the genus of *Tinospora*. Clearly one of ordinary skill in the art would have contemplated *Tinospora cordifolia* as one of the species in the *Tinospora* genus to be used for the treatment of urinary tract infections. Even though Upadhyay teaches that *Tinospora cordifolia* was used for ex vivo expansion of the number of hematopoietic cells, Upadhyay still makes it clear that *Tinospora sp.* of cells were used for treating urinary tract infections. Since clearly *Tinospora cordifolia* was being contemplated in the reference, then clearly one having ordinary skill in the art would have been motivated to use *Tinospora cordifolia* since this plant was clearly contemplated at the time the invention was made for its usefulness and specifically *Tinospora* species were known for their urinary tract infection treatment ability thus making it obvious and well within the purview of the ordinary artisan in an effort to optimize the desired results to use specifically *Tinospora cordifolia* to treat urinary tract infections since such plants such as *Tinospora* species were known to treat urinary tract infection. Clearly *Tinospora cordifolia* was contemplated and was clearly within the purview of the ordinary artisan to use since it is such a well known plant for

many uses. Further, it clearly would have been within the purview of the ordinary artisan to use the extract for chronic recurrent urinary tract infections since the extract is already noted to be used for urinary tract infections and thus to use the extract for chronic recurrent urinary tract infections is obvious since knowing that the extract is widely used in Indian medicine for urinary tract infections it would also be obvious to use the extract for chronic recurring infections since these type of infections are chronic many times and do reoccur.

Applicant argues that Upadhyay does not teach the use of *Tinospora cordifolia* as an immunoadjuvant along with conventional antibacterial therapy in the treatment of recurrent urinary tract infections.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The applicant argues that while De Souza teaches use of the standardized extract of *Tinospora cordifolia* as an adjuvant therapy in patients with osteomyelitis, cancer, diabetes and respiratory system disorders but no reference is made to urinary tract infections.

De Souza was used was to show that an extract of *Tinospora cordifolia* is standardized by bioassay and is administered to humans. It was also used to show that the extract is administered along with conventional therapy such as penicillins. Since Upadhyay already establishes that plants of the *Tinospora* sp. such as *Tinospora cordifolia* are already known in traditional Indian medicine for treatment of urinary tract infections and De Souza establishes that standardized extracts of *Tinospora cordifolia* are known to be co-administered with antibacterial agents such as penicillins and since the urinary tract infections occur due to relapsing bacterial infections, then it clearly would have been obvious to use the penicillins with the *Tinospora cordifolia* since antibacterial agents such as penicillins would be obvious to use when one wants to treat a urinary tract infection which is due to relapsing bacterial infections. Note also that Upadhyay recognized the ability of *Tinospora cordifolia* as an anti-bacterial (anti-*E. coli*) as noted above.

Applicant next argues that the proper treatment of recurrent urinary tract infections is critical considering the resistance to conventional antibiotics and cites an article abstract in *Clinical Microbiology Infection*, but while the article is noted it does not establish any long felt need since applicant has not proved that antibacterial infections are a long felt need since they have been successfully

treated all the time. One article does not establish such an alleged long felt need. In fact, the art of record cited by this examiner establishes that using penicillins and the claimed *Tinospora cordifolia* would make sense as being used together since the claims are directed to treating renal disorders which are complicated or uncomplicated chronic recurrent urinary tract infections that are due to relapsing bacterial infections which would require antibiotics since one is trying to kill the bacteria thus an anti-bacteria formulation would be clearly obvious to use. The article is very broad in its nature and fails to establish the alleged long felt need. In fact, it states that there is a declining penicillin resistance, thus making it even more obvious to use penicillins since they would thus be effective against such bacteria.

Note that the references still meet the claims since the references clearly only use the one extract of *Tinospora cordifolia*.

Applicant argues that the instantly claimed invention administers *Tinospora cordifolia* as an immunoadjuvant in conjunction with conventional antibacterial therapy. Applicant points to pages 16-19 and the Tables in the specification. While pages 16-19 and the tables are noted, the "unexpected results" are not commensurate in scope with the claimed invention since no amounts are given in the "unexpected results" and such the claims are not commensurate in scope

with the disclosed invention which is allegedly unexpected. Clearly a specific amount of extract yielded the disclosed results in pages 16-19 and the tables.

Applicant further argues long felt need and provides additional references. The invention is not a cure of chronic recurrent urinary tract infections. There are existing treatments for chronic recurrent urinary tract infections, thus applicant is not the first to offer a treatment for such conditions, thus applicants have not fulfilled a long felt need since others have designed treatments for chronic recurrent urinary tract infections (UTIs). While the additional references are noted, this still does not prove that there is a long felt need for treatment of chronic recurrent urinary tract infections since urinary tract infections are treated all the time. Applicant is not the first one to develop a treatment of chronic recurrent urinary tract infections, thus applicants have not met a long felt need.

Applicant also argues that Upadhyay only discusses general treatment of UTIs and not allegedly treating chronic recurrent urinary tract infections. Clearly chronic recurrent UTIs are well within the purview of the ordinary artisan to treat since chronic recurrent urinary tract infections are UTIs which are simply in a more serious stage. One of ordinary skill in the art knowing that the claimed extract can treat UTIs would clearly include treating chronic recurrent urinary tract infections since they are clearly in the family of UTIs as being a more severe form of UTIs.

To use an antibacterial such as amoxicillin is obvious since it is noted in De Souza to use penicillins as conventional therapy with the extract and to use a well known penicillin such as amoxicillin is well within the purview of the ordinary artisan since amoxicillin is one of the well known penicillins. Thus, making it obvious to use the extract along with conventional antibacterial therapy (penicillin).

Applicant argues that De Souza uses the extract in patients with osteomyelitis but De Souza was used to show that an extract of *Tinospora cordifolia* is standardized by bioassay and that it was administered to humans. It is also taught that the extract is administered along with conventional therapy such as penicillins. Thus Upadhyay clearly shows the use of the extract with UTIs and De Souza shows that such extracts are well known in the art to be standardized by bioassay.

Next applicant argues that Upadhyay only allegedly teaches treatment of UTIs and that one of ordinary skill in the art would not have considered its use as an immunoadjuvant. While this is noted to use a well known antibiotic such as a penicillin is well known in the art and would have been obvious to combine with another known antibacterial such as the claimed extract which is recognized to be a treatment for UTIs. To use the extract for chronic recurrent urinary tract infections is obvious because as stated above, one of ordinary skill in the art

knowing that the claimed extract can treat UTIs would clearly include treating chronic recurrent urinary tract infections since they are clearly in the family of UTIs as being a more severe form of UTIs.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/
Primary Examiner, Art Unit 1655

